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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,677	10/06/2004	Mark Parrington	API-01-20-US	4967
7590	06/12/2009		EXAMINER	
Patrick J Halloran			AEDER, SEAN E	
Aventis Pasteur Inc				
Intellectual Property Kenerr Bldg			ART UNIT	PAPER NUMBER
One Discovery Drive				
Swiftwater, PA 18370			1642	
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			06/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,677	Applicant(s) PARRINGTON ET AL.
	Examiner SEAN E. AEDER	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 May 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30, 36 and 38-50 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 36 and 44 is/are allowed.

6) Claim(s) 1-30, 38-43, and 45-50 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application

6) Other: _____

Detailed Action

The Amendments and Remarks filed 5/18/09 in response to the Office Action of 11/17/08 are acknowledged and have been entered.

Claims 1-30, 36, and 38-50 are pending and are currently under examination.

Response to Arguments

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-30 and 38-43 remain rejected under 35 U.S.C. 101 for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Claims 1-30 and 38-43, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The term "expression vector" does not indicate the hand of man is required. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". *See MPEP 2105*.

In the Reply of 5/18/09, Applicant argues that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences. Applicant

further argues that compositions comprising expression vectors and pharmaceutical compositions are not naturally occurring.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the sequence of SEQ ID NO:28 is not naturally occurring and differs from previously known CEA sequences, not every DNA sequence which has occurred naturally or will occur naturally is known. Therefore, polynucleotides comprising SEQ ID NO:28 encompass naturally occurring polynucleotides which either have or will occur. In regards to the argument that comprising expression vectors are not naturally occurring, viruses are naturally occurring expression vectors. In regards to the argument that pharmaceutical compositions are not naturally occurring, claims reciting that a product is a pharmaceutical composition indicates an intended use and is not considered a limitation to a claim.

It is noted that amending claims 1, 26, and 38 by placing the word "isolated" before "nucleic" would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-50 remain rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al (US Patent 5,833,975; 11/10/98) for the reasons stated in the Office Action of 11/17/08 and for the reasons set-forth below.

Paoletti et al teaches ALVAC poxvirus vectors comprising CEA antigen-encoding SEQ ID NO:145, which shares greater than 80% homology with instant SEQ ID NO:28, and the full complement thereof (see abstract and sequence comparison below, in particular). Paoletti et al further teaches said vectors further comprising a nucleic acid sequences including the costimulatory molecule B7.1 (line 58 of column 14, in particular). Paoletti et al further teaches compositions comprising said vectors and pharmaceutically acceptable carriers (see line 22 of column 8, in particular). In regards to instant claims 45-50, it is noted that the nucleic acids of SEQ ID NO:145 includes all nucleic acids of 421-1490 of SEQ ID NO:28 (A, T, G, and C).

In the Reply of 5/18/09, Applicant argues that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28.

The arguments found in the Reply of 5/18/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that the amended claims are not anticipated by Paoletti et al because the amended claims related to nucleic acids comprising SEQ ID NO:28, the nucleic acids of claims 45-50 are not required to comprise the sequence set-forth as SEQ ID NO:28. Rather, the nucleic acids of claims 45-50 require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28. The nucleic

acids of claims 45-50 do not require an isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least nucleotides 421-1490 of SEQ ID NO:28 in any particular order.

It is noted the following amendments to claim 45 would obviate this rejection: "An isolated nucleic acid molecule comprising a CEA-encoding nucleic acid sequence including at least **the sequence set-forth by** nucleotides 421-1490 of SEQ ID NO.:28".

Comparison of instant SEQ ID NO:28 and SEQ ID NO:145 of Paoletti et al:

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Query Match          80.6%; Score 1697.8; DB 2; Length 2349;
  Best Local Similarity 88.1%; Pred. No. 0;
  Matches 1859; Conservative 0; Mismatches 247; Indels 3; Gaps
1;

Qy      1 ATGGAGTCTCCCTCGGCCCTCCCCACAGATGGTGCATCCCTGGCAGAGGTCTTGCTC 60
        |||||||.....|||||.....|||||.....|||||.....|||||.....|||||.....|||.
Db      184 ATGGAGTCTCCCTCGGCCCTCCCCACAGATGGTGCATCCCTGGCAGAGGTCTTGCTC
243

Qy      61 ACAGCCTCACTTCTAACCTCTGGAACCCGCCACACTGCCAAGCTCACTATTGAATCC
120
        |||||||.....|||||.....|||||.....|||||.....|||||.....|||||.....|||.
Db      244 ACAGCCTCACTTCTAACCTCTGGAACCCGCCACACTGCCAAGCTCACTATTGAATCC
303

Qy      121 ACGCGTTCAATGTCGCAGAGGGAAAGGAGGTGCTCTACTTGTCACAAATCTGCCAG
180
        |||||||.....|||||.....|||||.....|||||.....|||||.....|||||.....|||.
Db      304 ACGCGTTCAATGTCGCAGAGGGAAAGGAGGTGCTCTACTTGTCACAAATCTGCCAG
363

Qy      181 CATCTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
240
        |||||||.....|||||.....|||||.....|||||.....|||||.....|||||.....|||.
Db      364 CATCTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
423

Qy      241 GGATATGTAATAGGAACCTAACAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
300
        |||||||.....|||||.....|||||.....|||||.....|||||.....|||||.....|||.
Db      424 GGATATGTAATAGGAACCTAACAGCTACCCAGGGCCCGCATACAGTGGTCGAGAGATA
483

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Art Unit: 1642

Qy 360	301 ATATACCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAACATGACACAGGATTCTAC
Db 543	484 ATATACCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAACATGACACAGGATTCTAC
Qy 420	361 ACCCTACACGTATAAAGTCAGATCTTGTGAATGAAGAACACTGGCCAGTTCCGGGTA
Db 603	544 ACCCTACACGTATAAAGTCAGATCTTGTGAATGAAGAACACTGGCCAGTTCCGGGTA
Qy 480	421 TACCCGGAACCTCCCTAAAGCCTCTATTAGCTCCAATAATAGTAAGCTGTGCAAAGACAAA
Db 663	604 TACCCGGAGCTGCCAAGCCCTCCATCTCAGCAACACTCCAAACCCGTGGAGGACAAG
Qy 540	481 GATGCCGTCGCTTTACATGCGAGCCGAAACTCAAGACGCAACATATCTCTGGTGGGTG
Db 723	664 GATGCTGTGGCCTTCACCTGTGAACCTGAGACTCAGGACGCAACCTACCTGTGGTGGGTG
Qy 600	541 AACAAACAGTCCCTGCCTGTGTCCTAGACTCCAACCTCAGCAACGGAAATAGAACTCTG
Db 783	724 AACAAATCAGAGCCTCCGGTCAGTCCCAGGCTGCAGCTGTCCAATGGCAACAGGACCC
Qy 660	601 ACCCTGTTAACGTGACCAGGAACGACACAGCAAGCTACAAATGCGAAACCCAAATCCA
Db 843	784 ACTCTATTCAATGTCACAAGAAATGACACAGCAAGCTACAAATGTGAAACCCAGAACCCA
Qy 720	661 GTCAAGGCCAGGGAGTCTGATTCACTGATTCTCAAGTGCTTACGGACCCGATGCTCCT
Db 903	844 GTGAGTGCCAGGCAGTCAGTCACTCTGAATGTCCTATGGCCGGATGCC
Qy 780	721 ACAATCAGCCCTCTAAACACAAGCTATAGATCAGGGAAAATCTGAATCTGAGCTGT
Db 963	904 ACCATTCCCTCTAAACACATCTTACAGATCAGGGAAAATCTGAACCTCTCCTGCCAC
Qy 840	781 GCGCTAGCAATCCTCCGCCAATACAGCTGGTTGTCAATGGCACTTCCAACAGTCC
Db 1023	964 GCAGCCTCTAACCCACCTGCACAGTACTCTGGTTGTCAATGGACTTCCAGCAATCC

Art Unit: 1642

Qy 900	841 ACCCAGGAACGTTCATTCCAAATTACCGTGAACAATAGGGATCCTACACGTGCCAA
Db 1083	1024 ACCCAAGAGCTCTTATCCCCAACATCACTGTGAATAATAGGGATCCTATACGTGCCAA
Qy 957	901 GCTCACAAATAGCGACACCGGACTCAACCGCACAACCGTGACGACGATTACCGTGAT---
Db 1143	1084 GCCCATAACTCAGACACTGGCCTCAATAGGACCAAGTCACGACGATCACAGTCTATGCA
Qy 1017	958 GAGCCACCAAAACCATTCATAACTAGTAACAATTCTAACCCAGTTGAGGATGAGGACGCA
Db 1203	1144 GAGCCACCCAAACCCCTCATCACCAGCAACAACTCCAACCCGTGGAGGATGAGGATGCT
Qy 1077	1018 GTTGCATTAACCTGTGAGGCCAGAGATTCAAATACCACTTATTTATGGTGGGTCATAAAC
Db 1263	1204 GTAGCCTAACCTGTGAACCTGAGATTCAAGAACACAACCTACCTGTGGTGGGTAATAAT
Qy 1137	1078 CAAAGTTGCCGGTTAGCCCCACGCTTGCGAGTTGCTTAATGATAACCGCACATTGACACTC
Db 1323	1264 CAGAGCCTCCCGTCAGTCCCAGGCTGCAGCTGTCATGACAACAGGACCCCTCACTCTA
Qy 1197	1138 CTGTCGGTTACTCGCAATGATGTAGGACCTTATGAGTGTGGCATTGAGATGAATTATCC
Db 1383	1324 CTCAGTGTACAAGGAATGATGTAGGACCTATGAGTGTGGAAATCCAGAACGAATTAAGT
Qy 1257	1198 GTTGATCACTCCGACCCCTTATCCTTAATGTTTGATGGCCAGACGACCCAACATA
Db 1443	1384 GTTGACCACAGCGACCCAGTCATCCTGAATGCTCTATGGCCAGACGACCCACATT
Qy 1317	1258 TCTCCATCATACACCTACTACCGTCCGGCGTGAACCTTGAGCCTTCTTGCCATGCGACA
Db 1503	1444 TCCCCCTCATACACCTATTACCGTCCAGGGGTGAACCTCAGCCTCTCCGTCCATGCGACCC
Qy 1377	1318 TCCAACCCCCCTGCACAGTACTCCTGGCTGATTGATGGAAACATTCACTCAGCAGCA
Db 1563	1504 TCTAACCCACCTGCACAGTATTCTGGCTGATTGATGGAAACATCCAGCAACACACAA

Art Unit: 1642

Art Unit: 1642

Qy 1977	1918 TTTATGCCAAAATCACGCCAATAATAACGGGACCTATGCCCTGTTTGCTCTAACTTG
Db 2163	2104 TTTATGCCAAAATCACGCCAATAATAACGGGACCTATGCCCTGTTTGCTCTAACTTG
Qy 2037	1978 GCTACTGGCCGCAATAATTCCATAGTCAGAGCATCACAGTCTCTGCATCTGGAACCTCT
Db 2223	2164 GCTACTGGCCGCAATAATTCCATAGTCAGAGCATCACAGTCTCTGCATCTGGAACCTCT
Qy 2097	2038 CCTGGTCTCTCAGCTGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTGGGTTGCT
Db 2283	2224 CCTGGTCTCTCAGCTGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTGGGTTGCT
Qy	2098 CTGATATAG 2106
Db	2284 CTGATATAG 2292

Allowable Subject Matter

Claims 36 and 44 are allowed.

Summary

Claims 1-30, 38-43, and 45-50 are rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/

Application/Control Number: 10/510,677

Art Unit: 1642

Primary Examiner, Art Unit 1642

Page 11